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EXAMINER

SMITH, RUTH S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3737

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/539,015

**Applicant(s)**

WINSTON ET AL.

**Examiner**

Ruth S Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2004 has been entered.

***Specification***

The disclosure is objected to because of the following informalities: On page 6, line 21, it is unclear as to how the first end 64 can be glued to guide wire head 32 as disclosed. On page 11, line 13, "Computer" should be "computer". On pages 11-12, reference numerals 100, 102, 104, 106, 108, 110 are not seen in the figures. Appropriate correction is required.

***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Reference numerals 100, 102, 104, 106, 108, 110. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose that the guide wire distal end comprises at least one stationary fiber of the interferometric guidance system. It is unclear as to what the fiber is stationary with respect to. The fiber is part of the apparatus which is guided into the body so that it must inherently involve movement of the fiber and therefore cannot be stationary.

Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is vague and indefinite in that it is unclear as to how the fiber set forth on line 5 of claim 1 relates to the first fiber set forth in claim 2.

### ***Claim Objections***

Claims 2-10,14-18 are objected to because of the following informalities: In claim 2, "further" should be inserted before "comprises" on line 2. In claim 5, line 2, "detecting" should be "generating". In claim 6, line 1, "wherein" should be inserted before "said circuit". In claim 6, line 2, "detecting" should be "generating". In claims 7, 8, "said first optic fiber" lacks antecedent basis. In claims 9,10, "said second optic fiber" lacks antecedent basis. In claim 14, the meaning of line 9 is unclear. It appears that applicant inadvertently deleted the term "examining". It is unclear as to how the step of "performing a Doppler shift analysis set forth in claim 14 relates to the step of generating a Doppler shift analysis as set forth in claim 17. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tearney et al. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22,32) wrapped around piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). The fiber which transmits light to the tissue includes an end coupled to a distal end of the endoscope as seen in figure 6.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5,6,12,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tearney et al in view of Peterson et al. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22,32) wrapped around piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). Tearney et al fails to disclose the use of a frequency to voltage converter. Peterson et al disclose an apparatus for performing Doppler blood flow studies wherein processing circuitry (590) includes a frequency to voltage converter (col. 9, lines 18-20). It would have been obvious to one of ordinary skill in the art to have modified the apparatus of Tearney et al such that it includes a frequency to voltage converter to facilitate computerized processing of frequency signals as is well known in the art.

Claims 14,18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izatt et al in view of Tearney et al. Izatt et al disclose performing Doppler shift analysis on signals generated by an interferometric system examining a sample including blood vessel to determine the velocity of blood. Izatt et al fails to disclose the specifics of the apparatus used to perform the method. Tearney et al disclose a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information. Tearney et al further disclose an illumination source (2), first and second optical fibers (22,32) wrapped around piezoelectric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). The guidewire distal end is considered to be stationary with respect to at least one axis of the endoscope in which it is positioned. It would have been obvious to one skilled in the art to have modified Izatt et al such that it includes the specific apparatus of Tearney for generating the Doppler shift information. The modification merely involves the substitution of one known type of interferometric

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system for another for obtaining information regarding the velocity of blood flow through a vessel.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izatt et al in view of Tearney et al as applied to claim 14 above, and further in view of Swanson et al. Swanson et al disclose a method for performing optical measurements including Doppler shift analysis and using either linear or sinusoidal changes in path length. It would have been obvious to one skilled in the art to have further modified Izatt et al to include the Doppler shift analysis as taught by Swanson et al. Such a modification merely involves the substitution of one type of Doppler shift analysis of optical signals for another.

#### ***Response to Arguments***

Applicant's arguments filed March 19, 2004 have been fully considered but they are not persuasive. The fiber which transmits light to the tissue includes an end coupled to a distal end of the endoscope as seen in figure 6.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Ruth S. Smith", with a stylized, cursive script.

Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS